UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA [UNDER SEAL],	CIVIL ACTION NO.
PLAINTIFF,	---
v.	**FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**
[UNDER SEAL],	
DEFENDANT.	

FILED
U.S. DISTRICT COURT
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FIRST AMENDED COMPLAINT

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *EX REL.* CHARLES BATES, III and CRAIG PATRICK PLAINTIFFS, *v.* KYPHON, INC. and SISTERS OF CHARITY HOSPITAL, DEFENDANTS.	CIVIL ACTION NO. 05-CV-6568 CJS(f) **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT

Plaintiffs and qui tam relators Charles M. Bates and Craig Patrick, through their attorneys Phillips & Cohen LLP and Chamberlain & D'Amanda, for their Complaint against Kyphon, Inc. allege as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent statements, records, and claims made and caused to be made by the defendant and/or its agents and employees in violation of the Federal False Claims Act, 31 U.S.C. §3729 et seq., ("the FCA" or "the Act").

2. This qui tam case is brought against defendant Kyphon, Inc. for conducting a fraudulent marketing and inducement campaign that foreseeably caused to be presented to the Medicare program false or fraudulent claims for inpatient hospital admissions, procedures and

related costs. As a direct result of defendant's improper practices, the federal Treasury has been damaged in substantial amount.

3. Since 1999, Kyphon has conducted an aggressive marketing campaign to sell its costly equipment and medical devices, including an orthopedic bone tamp and bone cement, for use in kyphoplasty procedures. From the beginning, the largest obstacle Kyphon has faced to sales of its product was the sky high cost it placed on its equipment relative to the reimbursement available for the kyphoplasty procedure for hospitals under outpatient admissions.

4. Rather than lowering its costs or reducing its profit margin of over 90% on its expensive equipment, Kyphon initiated a coordinated nationwide sales campaign to induce hospitals to allow eligible physicians to perform kyphoplasty and to purchase its expensive equipment. Kyphon markets to hospitals the opportunity to gain high reimbursement from Medicare by admitting patients for unnecessary inpatient overnight hospital stays. Specifically, Kyphon has undertaken a massive effort to induce hospitals to admit patients for one night stays by marketing to hospitals the significant revenue to be derived by coding the Medicare Part A claim for the kyphoplasty procedure and inpatient stay under mostly DRGs 233, 234, and 216.

5. For the vast majority of patients, kyphoplasty can be safely performed as an outpatient procedure. Inpatient admission is not medically necessary. However, as a result of Kyphon's marketing campaign, of the 150,000 kyphoplasty procedures performed since 1999, approximately 80-90% have been performed as expensive and clinically unnecessary inpatient procedures.

6. In addition to inducing unnecessary and expensive inpatient procedures, Kyphon has knowingly induced physicians to perform kyphoplasty by encouraging physicians to submit

claims for reimbursement for kyphoplasty procedures using "upcoded" procedure codes. From 1999-2005, Medicare carriers had divergent policies on coverage for kyphoplasty. Some carriers refused to cover the procedure and designated it as investigational/ experimental or directed providers to submit claims using "unlisted" procedure codes.

7. To avoid restrictions on reimbursement imposed by Medicare carriers, Kyphon instructed physicians to submit claims for reimbursement under CPT codes designated for "open reduction" of a bone fracture. Kyphoplasty, however, is not an open procedure but is performed percutaneously. Kyphon's misleading sales campaign was designed to induce doctors to submit claims for kyphoplasty as an "open procedure" in areas of the country where Medicare carriers would not cover the procedure or where the carrier directed that kyphoplasty be coded as an unlisted procedure.

8. Kyphon's fraudulent marketing scheme also includes giving additional kickbacks and inducements for physicians and hospitals to obtain increased sales of kyphoplasty products. As an additional inducement, Kyphon markets to physicians and hospitals a tool for performing bone biopsies during the kyphoplasty procedure. Kyphon's primary marketing message to sell bone biopsy procedures to physicians and hospitals is that it will provide additional revenue to hospitals by allowing the hospital to admit patients for overnight stays under DRG 216. Kyphon also advises any reluctant physicians that they must perform bone biopsies on every patient regardless of medical history or condition.

9. Kyphon also provides physicians and hospitals with other tangible and in-kind services to induce sales of its products. Kyphon sales representatives provide free Kyphon equipment to hospitals. Free equipment, in effect, increases the hospital's reimbursement for the

procedure as it reduces the hospital's supply costs. By increasing the hospital's revenues, providing free equipment creates an additional inducement to perform an increased numbers of kyphoplasty procedures and to admit more patients for unnecessary inpatient stays.

10. Kyphon also provides certain high-performing physicians with marketing support including assigning full time "Spine Education Specialists" to selected physicians, usually surgeons, who perform kyphoplasty. The job of the "Spine Education Specialists" is to work with the top ten referring physicians to identify patients and to refer these patients to selected surgeons who perform kyphoplasty. This in-kind marketing support by SES or sales representatives provides an extremely valuable benefit for the surgeons in marketing their practice to primary care physicians able to refer patients. This marketing support also promotes performance of additional kyphoplasty procedures and purchase of Kyphon products.

11. The FCA was originally enacted in 1863, and was substantially amended in 1986 by the False Claims Amendments Act, Pub.L. 99-562, 100 Stat. 3153. Congress enacted the 1986 amendments to enhance and modernize the Government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of Government frauds to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the Government's behalf.

12. The Act provides that any person who presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used false records and statements to induce the Government to pay or approve false and fraudulent claims, is liable for a civil penalty ranging from $5,500 up

to $11,000 for each such claim, plus three times the amount of the damages sustained by the federal Government.

13. The Act allows any person having information about false or fraudulent claims to bring an action for himself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time). Based on these provisions, qui tam plaintiffs and relators Charles Bates and Craig Patrick, seek through this action to recover damages and civil penalties arising from the defendant's knowing fraud on the U.S. Government.

II. PARTIES

14. Plaintiff/relator Charles Bates III, is a resident of Birmingham, Alabama. Mr. Bates is a former employee of Kyphon, Inc. Mr Bates began his employment as a Spine Consultant Field Sales Trainer for Kyphon in August 2001. Mr. Bates was one of the first local sales representative for Kyphon before its initial public offering. His responsibilities included developing markets in Alabama and the Florida Panhandle region. As a Spine Consultant, Mr. Bates was responsible for developing relationships with key surgeons in his region, managing surgeon education and training, and coordinating reimbursement initiatives with physicians and hospitals. Mr. Bates was also responsible for establishing new accounts with hospitals, assisting hospitals and physicians with coding and reimbursement questions, and marketing the local surgeon "champions" to referring physicians and potential patients. Business in Mr. Bates's territory grew from $16,000 per month to over $200,000 per month in nine months.

15. Mr. Bates became a Regional Sales Manager in July 2002. He managed sales

during a period of rapid expansion for Kyphon and worked with other Regional Sales Managers, Area Directors, Vice Presidents of Sales, and Reimbursement staff to implement and develop corporate strategies, maintain aggressive growth, and manage profitability of his region. Mr. Bates was given an award for achieving his sales goals in eight consecutive quarters. Mr. Bates' employment with Kyphon ended in July 2005. Prior to being employed by Kyphon, Mr. Bates worked in sales positions at Guidant, Inc., Baxter Healthcare Corporation, and Merit Medical Systems, Inc.

16. Plaintiff/relator Craig Patrick is a resident of Hudson, Wisconsin. Mr. Patrick recently resigned from his employment with Kyphon as a Reimbursement Manager. Craig Patrick is an expert in the managed care and sales arenas with extensive experience working with Medicare, Medicaid, and large third party payers. Mr. Patrick has been involved with sales and reimbursement within the healthcare industry for over ten years.

17. At Kyphon, Relator Patrick's responsibilities included developing and executing strategic plans to improve coverage and reimbursement of kyphoplasty. In addition, he worked directly with medical directors of Medicare carriers and private payers to ensure reimbursement for kyphoplasty. Mr. Patrick also handled large key accounts within the U.S. to gain further acceptance of kyphoplasty from a reimbursement perspective, including hospitals and large health systems. Mr. Patrick supported the field sales group with direct contact with hospitals, physicians, Medicare carriers and private payers to clear reimbursement hurdles.

18. Kyphon Inc. is a medical device company focused on the design, manufacture and marketing of instruments used in minimally invasive therapies for the treatment and restoration of spinal anatomy. Kyphon is currently marketing surgical tools that use its proprietary balloon

technologies for the repair of spinal fractures. Kyphon markets its products through sales representatives in the United States, and through sales representatives, distributors and agents in its international markets. The Company is headquartered in Sunnyvale, California, incorporated in Delaware, and has subsidiaries in many major countries in Europe, Canada and Japan.

19. Kyphon was founded in 1994 and operations commenced in September 1996. In January 1999, the company initiated limited direct sales of its first commercial products to several major medical centers. By May 2000, it had commenced full commercial introduction in the United States.

20. Defendant Sisters Of Charity Hospital is located at 2157 Main Street in Buffalo, New York. Sisters of Charity is owned by Catholic Health System. Catholic Health System, formed in 1998 and provides health care to Western New Yorkers across a network of four hospitals, ten primary care centers, nine diagnostic and treatment centers, a free standing surgery center, eleven long term care facilities, adult homes, home care agencies, counseling services, social service, and behavioral health programs. One of the two largest providers of health care in Western New York, Catholic Health System has 8,000 employees and 1,200 physicians.

21. Currently there are over 4,500 orthopaedic surgeons, neurosurgeons, interventional radiologists and interventional neuroradiologists in the United States who specialize in treating the spine and now perform balloon kyphoplasty using Kyphon's products. Over 175,000 fractures in 150,000 patients worldwide have been treated with balloon kyphoplasty to date.

22. As a result of Kyphon's high cost for its equipment and rapid expansion it has

reported enormous profits over the past six years. The profit margin on Kyphon products ranges between 87% and 92%.

III. JURISDICTION AND VENUE

23. This Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. §1331 and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. §3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

24. This Court has personal jurisdiction over the defendant pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the defendant has at least minimum contacts with the United States. Moreover, the defendant can be found in, resides in or transacts or has transacted business in the Western District of New York.

25. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because the defendant can be found in, and transacts or has transacted business in the Western District of New York. Specifically, defendant has marketed its products to Buffalo General Hospital, Millard Fillmore Gates Hospital, Roswell Park Cancer Institute, and Sisters of Charity Hospital. These hospitals have purchased products and performed Kyphoplasty procedures as described in this Complaint.

IV. BACKGROUND

A. THE MEDICARE PROGRAM

26. Medicare is a federally-funded health insurance program primarily benefitting the elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted. Medicare, the nation's largest health insurance program, provides health insurance to people age 65 and over, those who have end-stage kidney failure, and certain people with disabilities.

27. Medicare Part A (the Basic Plan of Hospital Insurance) covers the cost of hospital inpatient stays and post-hospital nursing facility care. Medicare Part B (the Voluntary Supplemental Insurance Plan) covers the costs of physician services, certain pharmaceutical products, diagnostic tests and other medical services not covered by Part A.

28. The Centers for Medicare and Medicaid Services (CMS) administers Medicare but much of the daily administration and operation of the Medicare program is managed through contracts with private insurance companies that operate as fiscal intermediaries. Fiscal Intermediaries are responsible for accepting claims for reimbursements under Medicare Part A (and some claims under Part B), and making payments for such claims. "Medicare Carriers" are responsible for accepting and paying claims for reimbursements under Medicare Part B

29. In New York, Empire Medicare Services is the Part A Fiscal Intermediary and, in Western New York, Blue Cross/ Blue Shield of Western New York is the Part B Medicare Carrier.

30. Under Medicare, different settings of care have different payment systems. In the

hospital inpatient setting where Medicare is the payer, the payment amount is determined by the Diagnosis-Related Groups, or DRGs. DRGs are a prospective payment system, meaning clinically similar diagnoses and/or procedure codes map to a DRG which then has a pre-determined reimbursement rate. (Clinically similar diagnoses and procedures naturally have similar resource utilization.). A DRG's pre-determined reimbursement rate is paid to the hospital regardless of how long the patient is admitted or the number of services provided.

31. On discharge of Medicare beneficiaries from a hospital, the hospital submits claims for interim reimbursement for items and services delivered to those beneficiaries during their hospital stays. 42 C.F.R. §§ 413.1, 413.60, 413.64. Hospitals submit patient-specific claims for interim payments on a Form CMS UB-92.

32. As a prerequisite to payment for Medicare, CMS requires hospitals to submit annually a Form CMS-2552 (previously Form HCFA-2552), more commonly known as the Hospital Cost Report. Cost Reports are the final claim that a provider submits to the fiscal intermediary for items and services rendered to Medicare beneficiaries.

33. After the end of each hospital's fiscal year, the hospital files its Hospital Cost Report with the fiscal intermediary, stating the amount of reimbursement the provider believes is due for the year. See 42 U.S.C. § 1395g(a); 42 C.F.R. § 413.20; see also 42 C.F.R. § 405.1801(b)(1). Medicare relies on the Hospital Cost Report to determine whether the provider is entitled to more reimbursement than already received through interim payments, or whether the provider has been overpaid and must reimburse Medicare. 42 C.F.R. §§ 405.1803, 413.60, and 413.64(f)(1).

34. Medicare payments for inpatient hospital services are determined by the claims

submitted by the provider for particular patient discharges (specifically listed on UB-92s) during the course of the fiscal year. On the Hospital Cost Report, this Medicare liability for inpatient services is then totaled with any other Medicare liabilities to the provider. This total determines Medicare's true liability for services rendered to Medicare beneficiaries during the course of a fiscal year. From this sum, the payments made to the provider during the year are subtracted to determine the amount due the Medicare program or the amount due the provider.

35. Medicare has the right to make retroactive adjustments to Hospital Cost Reports previously submitted by a provider if any overpayments have been made. 42 C.F.R. § 413.64(f).

36. Every Hospital Cost Report contains a "Certification" that must be signed by the chief administrator of the provider or a responsible designee of the administrator.

37. In September 1994, Medicare revised the certification provision of the Hospital Cost Report to state:

> I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

Form HCFA-2552-92.

38. In or about 1996, the Hospital Cost Report form was revised again to state:

Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine, and/or imprisonment under federal law. Furthermore, if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

39. Physician services provided while the patient is admitted to the hospital are billed

and reimbursed separately from DRGs. Physician services are reimbursed through a payment system called Resource-Based Relative Value Scale (RBRVS). In the RBRVS system, payments for services are determined by the resource costs needed to provide them. The cost of providing each service is divided into three components: physician work, practice expense, and professional liability insurance (malpractice). Payments are calculated by multiplying the combined costs of a service by a conversion factor (a monetary amount that is determined by CMS). Payments are also adjusted for geographical differences in resource costs.

40. RBRVS payments are based on the Healthcare Common Procedure Coding System (HCPCS). HCPCS is a standardized coding system designed to ensure that Medicare, Medicaid and other federal health care programs pay for services rendered to patients by attending physicians and other healthcare professionals in accordance with payment schedules tied to the level of professional effort required to render specific categories of medical care. To ensure normalization of descriptions of medical care rendered and consistent compensation for similar work, both programs tie levels of reimbursement to standardized codes.

41. The Current Procedural Terminology ("CPT") codes are Level I HCPCS codes and are published and updated annually by the American Medical Association ("AMA").

42. Base CPT codes are five-digit numbers organized in numeric sequences that identify both the general area of medicine to which a procedure relates (such as "Evaluation and Management," "Anesthesiology," "Surgery," "Radiology," or general "Medicine") and the specific medical procedures commonly practiced by physicians and other health care professionals working in that field.

43. The instructions that accompany the CPT manual direct providers "not select a

CPT code that merely approximates the service provided." Rather, if no accurate service procedure or service exists among the standard CPT codes, providers are instructed to "report the service using the appropriate unlisted procedure or service code" (*i.e.*, the special CPT codes provided for use when none of the standard CPT codes reasonably and adequately describes the specific procedure or service provided).

44. Codes listed after each subsection in the CPT Manual and ending in -99 are "unlisted" codes. Correct code assignment occurs after the documentation for the claim is reviewed by the carrier

45. Physicians typically submits claims for professional services on Form CMS-1500. The claim form sets forth the diagnostic code describing the patient's presenting condition and the procedural codes. On the claim form, the physician certifies that the services were "medically indicated and necessary to the health of the patient ...."

46. Payments for hospitals in the outpatient setting also bundle items and services so that hospital providers are paid for the procedures performed including the cost of equipment. Hospitals use APC Codes (Ambulatory Payment Classifications) to bill for costs associated with outpatient services.

47 In addition to compliance with other national or local coverage criteria, Medicare requires as a condition of coverage that services be reasonable and medically necessary. 42 U.S.C. § 1395y(a)(1)(A).

48. Providers must provide economical medical services and, then, provide such services only where medically necessary. 42 U.S.C. § 1320c-(a)(1).

49. Providers must provide evidence that the service is medically necessary as appropriate. . 42 U.S.C. § 1320c-5(a)(3).

50. Providers must ensure that services provided are not substantially in excess of the needs of such patients. 42 U.S.C. § 1320a-7(b)(6)&(8).

B. THE ANTI-KICKBACK STATUTE

51. The federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

52. The Anti-Kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, medical device companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend products that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a company that has as one of its purposes inducement of a physician to perform additional procedures using the company's products.

53. Violation of the Anti-Kickback statute subjects the violator to exclusion from

participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§1320a-7(b)(7), 1320a-7a(a)(7).

C. TREATMENT OF VERTEBRAL COMPRESSION FRACTURES

54. Osteoporosis is a disease in which bones become fragile and are more likely to break. National Osteoporosis Foundation (www.nof.org). If not prevented or if left untreated, osteoporosis can progress painlessly until a bone breaks. Fractures occur typically in the hip, spine, and wrist.

55. When a bone in the spine collapses, it is called a vertebral compression fracture (VCF). These fractures happen most commonly in the thoracic spine (the middle portion of the spine), particularly in the lower vertebrae.

56. Spinal or vertebral body compression fractures (VCFs) can have serious consequences, including loss of height, severe back pain, and deformity.

57. According to the Food and Drug Administration, osteoporosis causes more than 700,000 spinal fractures each year in the United States.

58. If left untreated, a spinal fracture can lead to subsequent fractures, often resulting in a condition called kyphosis. Kyphosis is signified by the "dowager's hump," or rounded back. Kyphosis can compress the chest and abdominal cavity with many potential health consequences. (www.kyphon.com)

59. Osteoporosis affects post-menopausal more women most severely More than one-fourth of women over age 65 will develop a vertebral fracture due to osteoporosis. Decreased mobility from compression fractures accelerates bone loss. High doses of pain medication, especially narcotic drugs, further limit functional ability.

60. Traditional treatment for fractures of the spine was immobilization (bed rest) with bracing and drugs for the pain.

61. In 1984, a surgical technique to reduce the pain and loss of function associated with vertebral fractures called "percutaneous vertebroplasty" was developed in France.

62 In both vertebroplasty and the later-developed kyphoplasty, bone cement, usually polymethyl methacrylate, is injected percutaneously into the partially collapsed vertebral body under fluoroscopic guidance (fluoroscopy or CT).

63. Both vertebroplasty and kyphoplasty are minimally invasive procedures performed to treat persistent pain or instability resulting from vertebral compression fractures attributable to osteoporosis or neoplasms in the bone. The procedures may also be used to treat aggressive hemangiomas.

64. In vertebroplasty, the bone cement is injected in a semi fluid state.

65. Kyphoplasty is a modest innovation on the vertebroplasty procedure. In kyphoplasty, an inflatable bone tamp is introduced into the vertebra and inflated partially to restore vertical height before the cement is injected into the space. Once the vertebra is in the correct position, the balloon is deflated and removed. This process creates a void (cavity) within the vertebral body. In kyphoplasty, the cement may be injected under lower pressure and in a more viscous state than in vertebroplasty.

66. In kyphoplasty, the cavity is filled with a bone cement to support the surrounding bone and to prevent further collapse. The cement forms an internal cast that holds the vertebra in place. Generally, the procedure is done on both sides of the vertebral body.

67. Both the vertebroplasty and kyphoplasty procedures are of relatively short

duration. Medical-grade cement hardens quickly, over 10 to 20 minutes. A CT scan may be performed at the end of the procedure to check the distribution of the cement. The longest part of either procedure is the time involved in setting up the equipment and making sure the needle is positioned in the collapsed vertebra.

68. Both vertebroplasty and kyphoplasty may be safely performed as outpatient procedures. Inpatient stays at a hospital would only be expected for the rare cases if the patient is unusually frail or their other medical issues require further monitoring following the procedure. As a result, the vast majority of patients receiving vertebroplasty do so on an outpatient basis.

69. The FDA approved the KyphX Inflatable Bone Tamp Kyphon inflatable bone tamp with 510K status in 1998.

70. In April 2004, Kyphon received 510K clearance for KyphX HV-R to be used in vertebroplasty and kyphoplasty.

71. Prior to 2004, other bone cements and bone void-filling products with 510K clearance for use on hip and other bone fractures were used on spinal vertebra for kyphoplasty as an "off label" use.

72. Some recent published and peer reviewed articles have documented a lower complication rate with kyphoplasty than vertebroplasty and suggest that kyphoplasty may be a safer and more efficacious procedure than vertebroplasty.

73. According to Kyphon, there may be lower complication rates because of the ability to compact cancellous bone and to create a cavity reduces the potential for extravertebral cement leakage during balloon kyphoplasty. In addition, complications may be lower because of how viscous bone cement is delivered into a cavity under manual control.

74. Despite the fact that kyphoplasty has a lower complication rate than traditional

vertebroplasty, since 1999, Kyphon has aggressively marketed the kyphoplasty procedure to hospitals and physicians as a procedure that should be performed with an inpatient one-night stay to maximize the hospital's and physician's reimbursement. Through this strategy of marketing high rates of reimbursement through inpatient admission to hospitals, Kyphon has been able to reap significant profits from sales of its Kyphon products without reducing the price of its equipment to reflect available reimbursement rates for outpatient procedures.

D. MEDICARE COVERAGE OF KYPHOPLASTY

75. Typically, both vertebroplasty and kyphoplasty are recommended after less invasive treatments – such as bedrest, a back brace or pain medication—have been ineffective, or once medications have begun to cause other problems, such as stomach ulcers.

76. There is no National Coverage Determination for reimbursement for kyphoplasty.

77. Accordingly, the Medicare Carrier in each state determines the conditions for coverage and reimbursement of physician charges for kyphoplasty.

78. Prior to 2005, Medicare Carriers had varying policies on coverage of kyphoplasty procedures. Some covered the procedure using an unlisted code. Some covered the procedure on a case by case basis involving the presentation of medical necessity to the Carrier. Some refused to cover the procedure and classified it as investigational and experimental.

79. Kyphon has directed substantial effort to obtaining coverage for kyphoplasty procedures through the Medicare Carriers.

80. Currently, although criteria may differ slightly, every Medicare carrier has a policy that authorizes coverage of kyphoplasty.

81. A typical Local Coverage Determination is that issued by Noridian Administrative

Services, LLC effective May 15, 2005. Noridian is the Medicare Part B Carrier for Alaska, Arizona, Colorado, Hawaii, Iowa, Nevada, North Dakota, Oregon, South Dakota, Washington, and Wyoming. .

82. Under Noridian's coverage determination, kyphoplasty is deemed medically necessary for osteolytic vertebral mestasis and myeloma with severe back pain related to a destruction of the vertebral body and osteoporotic vertebral collapse with persistent debilitating pain which has not responded to accepted standard medical treatment for several weeks.

83. Noridian's coverage determination identifies certain contraindications for kyphoplasty unless medical record documentation supports the rationale for the procedure.

84. The Noridian coverage determination directs physicians on to bill claims for reimbursement under the unlisted code 22899

85. In New York, Empire Medicare Services currently has a Local Coverage Determination allowing for payment for kyphoplasty if the physician bills his or her service under the unlisted code 22899. Bone biopsies are bundled into the payment for the kyphoplasty procedure.

86. Until recently, typical reimbursement to hospitals for outpatient kyphoplasty, where available, was less than $500. In January 2005, reimbursement to hospitals for outpatient kyphoplasty increased to approximately $2000.

87. As alleged herein, Kyphon developed a marketing scheme to exploit high reimbursement under inpatient DRGs to persuade hospitals to perform kyphoplasty. DRG 234 pays hospitals approximately $6,000 and DRG 233 pays between $8000 and $10,000 depending on geography.

88. When a bone biopsy is performed during an inpatient Kyphoplasty, that procedure was billed under DRG 216. Until recently, DRG 216 paid even more than DRG 233 or DRG 234.

89. From 1999-2005 physicians who billed for kyphoplasty under the unlisted code as directed by may carriers were reimbursed approximately $550 for the procedure with approximately $270 for each additional vertebra.

90. Starting in January 2006, Medicare has designated specific CPT codes for kyphoplasty to replace the use of unlisted procedure CPT code 22899 in most states. The new codes are 22523 (percutaneous vertebral augmentation, including cavity creation, thoracic), 22524 (percutaneous vertebral augmentation, including cavity creation, lumbar), and 22525 for each additional thoracic or lumbar vertebral body.

91. Kyphon's kyphoplasty kits sells for approximately $3400. Kyphon's kit for a second vertebral level sells for approximately $2300.

V. ALLEGATIONS

A. KYPHON ILLEGALLY MARKETS ITS EQUIPMENT TO HOSPITALS AND PHYSICIANS TO MAINTAIN HIGH PROFITS

92. Since 1999, Kyphon has aggressively marketed Kyphoplasty as an inpatient procedure to induce hospitals to purchase their products.

93. According to Kyphon Reimbursement materials, Medicare is the single largest payer for kyphoplasty and pays for 85-90% of procedures performed.

94. In 2000, slightly more than 1,500 Kyphoplasty procedures were performed in the United States. In 2004 this number increased to over 48,000. It is estimated that 60,000 Kyphoplasty procedures will be performed in 2005.

95. Starting in 1999, Kyphon devised a strategy to market its products which would allow it to maximize profit for its products and avoid lowering the high prices of its products to meet the relatively low rates of reimbursement available for hospitals for kyphoplasty as an outpatient procedure.

96. Internal reports prepared by Kyphon sales representatives confirm that, since the inception of its marketing strategy in 1999, the largest challenge to selling Kyphon's products are relatively low rates of reimbursement for kyphoplasty as an outpatient procedure. Kyphon has made it clear to its sales and reimbursement personnel, including Relators, that it will not lower the price of its product and reduce its large profit margins.

1. Kyphon Can Safely Be Performed as an Outpatient Procedure in the Majority of Cases

97. Vertebroplasty had been performed successfully as an outpatient procedure by interventional radiologists and surgeons for many years.

98. Paid speakers for Kyphon, including physicians on the Kyphon "faculty," promote kyphoplasty as having a much lower complication rate than vertebroplasty. Kyphon chooses physician "faculty members" based on whether they bill kyphoplasty as an inpatient procedure and routinely perform bone biopsy during kyphoplasty. Physicians who billed "aggressively" would be chosen as Kyphon faculty and paid speaker fees.

99. Medicare refers to the guidelines for medical necessity for inpatient admission published by Interqual. Interqual guides hospitals to look at the severity of the patient's condition and intensity of the procedures in making the medical necessity determination.

100. When a hospital, through its credentialing committee, makes the decision to allow patients to be admitted to the hospital, the hospital should consider 1) the severity of the signs and symptoms exhibited by the patient, 2) the medical predictability of something adverse

happening to the patient, 3) the need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and 4) the availability of diagnostic procedures at the time when and at the location where the patient presents. Hospital Manual, Ch. II, §210 Covered Inpatient Hospital Services.

101. Under the Interqual data, or any other set of criteria for evaluating medical necessity of inpatient admission, admission of patients for a one night stay after kyphoplasty is not medically necessary in the vast majority of patients and not unless significant comorbidities can be documented.

102. Kyphon knew that such one night inpatient stays were, in the vast majority of cases, medically unnecessary. Kyphon also knew that unless hospitals recognized revenue from kyphoplasty, hospitals would be unlikely to purchase expensive Kyphon kits,

103. As a result, Kyphon chose to build its sales and profits by undertaking a fraudulent marketing campaign to persuade hospitals and physicians that kyphoplasty was to be performed with a one night inpatient admission. Kyphon did not choose to market kyphoplasty truthfully as an outpatient procedure or to advise hospitals that the patient could be admitted for an observation period of up to 23 hours. Instead, Kyphon exploited the DRG reimbursement scheme to ensure high revenue for target hospitals through unnecessary inpatient stays.

2. Kyphon Induces Hospitals and Physicians to Admit Kyphoplasty Patients for Unnecessary One-Night Inpatient Stays

104. Starting in 1999, Kyphon sales and marketing departments trained its sales representatives to market its equipments (and the kyphoplasty procedures) as a procedure that must be performed inpatient through a one night hospital stay.

105. Specifically, Kyphon managers including national sales representatives trained Relator Chuck Bates and hundreds of other typical sales representatives with Kyphon to sell hospitals on the profit to be derived by allowing physicians to perform kyphoplasty as an inpatient procedure with a one-night stay. Kyphon instructed its sales force to market kyphoplasty to hospitals as an inpatient procedure even though such inpatient admissions are, in the vast majority of cases, medically unnecessary.

106. When a patient with a known diagnosis enters a hospital for a specific minor surgical procedure that is expected to keep him in the hospital for only a few hours (less than 24), he is considered an outpatient for coverage purposes.

107. For patients that require observation after a procedure, outpatient admission for observation up to 23 hours is available and bills may be submitted to the Medicare carrier under Medicare Part B.

108. If Kyphoplasty is performed as an inpatient procedure, patients are admitted for an overnight stay at the hospital and the hospital will be paid under the DRG. The DRGs are set by Medicare based on the resource needs of an average patient with that set of disease or disorders.

109. Sales representatives, including Chuck Bates, were instructed to identify physicians, mostly surgeons, eligible to perform the kyphoplasty procedure and to arrange for training for those physicians.

110. In August 2001, Chuck Bates attended a sales training meeting at corporate headquarters in Sunnyvale, California for Kyphon where the sole focus of the reimbursement training was on kyphoplasty as an inpatient procedure.

111. Kyphon managers decided to focus on recruiting and training surgeons

as part of its initial strategy to increase inpatient admissions. Interventional radiologists had performed most vertebroplasty procedures safely for years as outpatient procedures in the radiology lab. Kyphon chose orthopedic surgeons and neurosurgeons as its target population instead of radiologists because surgeons generally have admitting privileges at hospitals. Also, surgeons tend to have greater influence than radiologists with hospital credentialing committees and with hospitalization utilization review and quality control managers.

112. The primary focus of the sales force training was on inducing hospitals to admit kyphoplasty patients as inpatients with a one night stay so as to maximize the hospital's revenue and to persuade more hospitals to purchase Kyphon products than would be purchased if procedures were outpatient.

113. Thus, as part of its strategy to induce purchase of Kyphon products and performance of kyphoplasty, Kyphon sales representatives met with both physicians, initially mostly surgeons, and relevant personnel at hospitals where the identified physician had admitting privileges.

114. Because kyphoplasty would be a new procedures for hospitals, a physician would have to apply for credentials to perform that procedure at the hospital. The credentialing committee would make a determination of whether the procedure could be safely and profitably performed at its hospital including whether there was insurance available for malpractice, whether the physician had been properly trained in the procedure, and whether reimbursement was available to make the procedure financially feasible.

115. As part of his duties as a typical Kyphon sales rep, Chuck Bates met with the

Chief Financial Officer or Materials Manager at a hospital where a targeted physician had admitting privileges and provided the hospital personnel with information about physician training and reimbursement for the procedure.

116. As part of the sales presentation to hospitals, Kyphon representatives would explain that the hospital should bill for the procedure by admitting the patient to the hospital and coding the claim to bill under DRG 233 or 234. DRG 233 would make more money for the hospital than under DRG 234.

117. Kyphon representatives would not advise hospitals that kyphoplasty could be safely performed as an outpatient procedures. In fact, on at least one occasion sales representatives advised hospitals that kyphoplasty could not be performed outpatient.

118. Kyphon representatives would also meet with coders and medical record departments to explain to them how to code and bill the hospital charges to ensure payment under DRG 233 (Other Musculoskeletal System and Connective Tissue or Procedure with cc) or 234 (Other Musculoskeletal System and Connective Tissue or Procedure without cc). Sales representatives were trained to work with hospital coders to ensure they used ICD codes that would track to DRG 233 and DRG 234. Sales representatives were instructed to work with physicians and codes to document as many co-morbidities as possible to support medical necessity for DRG 233.

119. Patients admitted inpatient under DRGs 233 and 234 have an average length of stay of 12-14 and 6-8 days according to data from New York's Fiscal Intermediary.

120. By persuading hospitals to admit patients for one night inpatient stays under DRGs 233 or 234, Kyphon sought to maximize reimbursement for hospitals by exploiting the high reimbursement rate under inpatient DRGs intended for much longer and costlier stays.

121. Sales materials provided to Relator Bates at his initial training in 2001 at Kyphon Headquarters directed sales representatives to advise hospitals to bill for the procedure as an inpatient admission under DRG 233 or 234. The sales material also referred to DRG 499 (Back and Neck Procedures with cc) and 500 (Back and Neck Procedures without cc). Although Kyphon initially promoted DRGs 499 and 500, by 2001 sales representatives were advised to instruct hospitals not to bill with DRGs 499 or 500 because hospital revenue could be optimized under DRG 233 or 234.

122. The sales training materials do not refer to hospitals obtaining outpatient reimbursement for kyphoplasty under APC codes. Kyphon had no intention of marketing kyphoplasty as an outpatient procedure.

123. Sales representatives also worked with hospital coders to make sure they coded these claims with the ICD-9 Diagnostic Code 733.13 (Pathologic Fractures of the Spine) and ICD-9 Procedure Codes 03.53 (Repair of Vertebral Fracture) and 78.49 (Osteoplastym other (includes vertebrae)) as instructed in sales training.

124. Kyphon sales representatives would be present in the Operating Room during kyphoplasty procedures. Sales representatives were taught to ask Operating Room nurses whether the patient had been admitted for an inpatient stay. If the patient had not been admitted, Kyphon sales representatives would arrange for the physician to sign orders for inpatient admission in the Operating Room.

125. If questioned in the Operating Room about the propriety of admitting the patient, Kyphon sales representatives would sometimes lie and tell physicians that no reimbursement was available to the hospitals from Medicare if performed as an outpatient and that Medicare only covered the procedure with an inpatient admission.

126. The entire goal of Kyphon's campaign to persuade hospitals to treat kyphoplasty as inpatient admission with a one night stay was to allow hospitals to profit from for performing increasing number of these procedures. In this way, Kyphon hoped to, and did, spur increasing sales of expensive Kyphon products. Kyphon's phenomenal sales growth was funded, in large part, by its successful efforts to assist hospitals to obtain reimbursement by admitting patients for unnecessary one night hospital stays under DRG codes designed typically for much longer hospital stays.

127. Sales training of sales representatives focused almost entirely on the issue of maximizing reimbursement for hospitals. In addition, techniques used to counter hospital officials who questioned whether the procedures could be performed inpatient were discussed between sales representatives and with sales managers and in regional and area teleconferences.

128. From time to time, hospital utilization review and case management personnel at some hospitals would object to admitting patients with one night stays. In that case, sales representatives were trained to counter these objections by arguing strenuously that it was medically necessary to admit patients for overnight stays to monitor them after kyphoplasty. Sales representatives were trained to suggest to hospital personnel that it would be unsafe to perform kyphoplasty as an outpatient procedures or even to hold the patient for observation with an outpatient admission.

129. Sales representatives distributed published articles to make the case that inpatient admission was medically necessary and that outpatient treatment would fall below the standard of care in the industry. These articles were written by physicians acting as paid consultants for Kyphon, including Dr. Isador Lieberman of the Cleveland Clinic.

130. After having made significant inroads in training surgeons on kyphoplasty and persuading hospital to allow for performance of kyphoplasty by working with them to claim reimbursement for unnecessary inpatient stays under DRGs 233 and 234, Kyphon began to train interventional radiologists (IR's) and interventional neuroradiologists (INR's) to perform kyphoplasty as well. Kyphon did not initially market to IRs and INRs because they do not admit large numbers of patients to the hospital on a regular basis and have performed vertebroplasty as a routine outpatient procedure Kyphon would only train radiologists who had hospital admission privileges.

131. Efforts by Kyphon to train radiologists to perform kyphoplasty as inpatient procedures have been extremely successful. Relator Patrick is aware of entire radiologist groups, such as St. Lukes in Milwaukee, that perform every kyphoplasty as an inpatient procedure. Dr. Paul Minor, the head of the department of St. Lukes told a group of radiologists during physician training that St. Lukes admits Kyphoplasty patients and keeps them overnight for reimbursement purposes. Dr. Paul Minor was a paid speaker of Kyphon at the time.

132. There is widespread awareness in the medical provider community that inpatient admission of patients for one night stays under DRGs 233 and 234 is fraudulent. In a meeting at a HCA hospital in Nashville, a Dr. Cruse stated to hospital administration officials that his reason for admitting kyphoplasty patients was so that the hospital would "make money" on the procedure. After that statement, Dr. Cruse was not permitted to perform kyphoplasty at that hospital.

133. Some sales representatives have been very successful in persuading physicians to admit all patients. Tim Walnofer, a former sales rep and Regional Sales Manager in Minnesota, persuaded Dr. Mark Meyers, now a leading doctor for kyphoplasty procedures in

Minnesota, to admit most of his patients to the hospital for one day triggering reimbursement under the DRG. Other radiologists have commented to Kyphon sales reps that Dr. Meyers is committing fraud.

134. Dr. Mark Meyers is part of Kyphon's "physician faculty" and is a paid speaker for Kyphon. Dr. Meyers prepared a powerpoint for presentation to other physicians in which he claims that Kyphon is a "sexier procedure " with a much lower complication rate (1% vs. 7.5%) than vertebroplasty. Dr. Meyers' presentation also states that Kyphon required inpatient admission.

135. Some physicians will perform kyphoplasty as an outpatient procedure for private pay patients, but perform kyphoplasty on all Medicare patients as an inpatient procedure. For example, Dr. Sammons of Huntsville, Alabama performs approximately thirty cases per quarter and selects inpatient or outpatient based on reimbursement levels for the hospital rather than medical necessity. Kyphon has continued to market kyphoplasty as an inpatient procedure (based on reimbursement potential) for Medicare patients even with physicians it knows safely perform kyphoplasty as an outpatient procedure on private pay patients.

136. A few years ago, Kyphon's Reimbursement Department was informed by physicians that the hospitals were claiming that they were losing money on Kyphoplasty procedures. Kyphon created a customized computer program that creates an "Economic Support Model" to demonstrate to hospitals that they should not lose money on inpatient kyphoplasty procedures. Regional sales managers and reimbursement managers were given copies of the software to customize an "Economic Support Model" for their hospital and to shows the exact reimbursement that the hospital will receive for each procedure under the DRG. Nowhere does the Economic Support Model suggest that kyphoplasty can be performed outpatient or evaluate

APC reimbursement. Instead, the Economic Support Model assumes that all kyphoplasty will be performed inpatient.

137. Sisters Of Charity Hospital allowed kyphoplasty patients to be admitted as inpatients in order to increase reimbursement. On June 25, 2003, Patient A, born July 25, 1922, was admitted to the hospital. The procedure including a biopsy was performed by Dr. Douglas Moreland and Dr. Gregory Czajka of Buffalo Neurosurgery, P.C.. Patient A was discharged from the hospital the following day on June 26, 2003. Reimbursement to the hospital was paid under DRG 216 in the amount of $11,044.60.

138. Between February 2002 and March 2004, at least four patients and likely more had kyphoplasty performed on them at Sisters of Charity Hospital and were admitted to the hospital for a one day stay.

139. As a reasonably foreseeable consequence of Kyphon's ongoing marketing of unnecessary inpatient admission and one night stays under DRG 233 and 234, numerous hospitals have submitted, and continue to submit, claims for reimbursement for unnecessary inpatient hospital stays under DRGs 233 and 234.

140. Claims for unnecessary inpatient admissions are false claims within the meaning of the Federal False Claims Act.

3. Kyphon Illegally Markets Reimbursement for Unnecessary Bone Biopsies

141. In an effort to further induce sales of their products, since approximately 2001, Kyphon sales representatives also have marketed to physicians and hospitals that bone biopsies could be performed during kyphoplasty to allow billing for inpatient admission under DRG 216 (Biopsies of musculoskeletal system connective tissue) and that hospitals can earn up

to $6000 more per inpatient procedure depending on geography and up to $9500 more if the addition of the bone biopsy converted the procedure to an inpatient admission.

142. Kyphon sales representatives encourage doctors to biopsy every patient, even if there is nothing to indicate the patient needs a biopsy. In February 2003, Kyphon released their "Bone Biopsy Device," a disposable, stainless steel tube and rod that can be used to take biopsy samples of bone for further evaluation.

143. Kyphon's purpose in developing the bone biopsy device was to assist its marketing strategy to convince doctors and hospitals that biopsies should be performed in every kyphoplasty to ensure that there were no undiagnosed pathologies in the bone. Kyphon sales representatives were instructed by their managers to tell doctors they should purchase and use the device for biopsies to "cover their tracks." The Kyphon biopsy tool costs $110.

144, Kyphon went so far as to market performance of the bone biopsy procedure with "scare" tactics and to suggest that physicians who did not perform routine biopsies could open themselves up to malpractice suits. Kyphon sales representatives were trained to say that up to 4% of biopsies will diagnose previously undiagnosed cancer.

145. Kyphon sales representatives were told by their managers that the purpose of the development of the biopsy device was two-fold: to provide a better biopsy and to cover the doctor with the hospitals on the reimbursement side. In addition, the doctors were told that if they performed a biopsy, they did not have to worry about finding a co-morbidity to make sure they were reimbursed under DRG 233, since DRG 216 paid more reimbursement to the hospital. The sales reps were also told to make sure that the coders picked up the biopsy to get to DRG 216.

146. Medicare will only reimburse for a biopsy if it is medically necessary.

However, Kyphon's strategy was to get the doctors to perform a biopsy on every patient regardless of medical necessity. Sales representatives were told to try to get the Bone Biopsy Devise listed on the card of the doctor's preferences for equipment in the operating room "for surgeons that want to use it on every case."

147. Marketing of the bone biopsy procedure was successful. In early 2003, sales representative David Munro stated that his biggest issue regarding HCA hospitals was reimbursement but that "the bone biopsy has saved the day." According to internal documents, Mr Munro explained, "I worked a long time with the OR, CFO and Medical Records trying to get to the right DRG (233) for the hospital to approve the surgeons use of the IBT. The use of the new bone biopsy device allowed the use of DRG 216 with the 3M software. The two HCA hospitals (Ocala Regional and Tallahassee Community) are excited about reimbursement and want more cases."

148. In early 2005 Medicare reduced reimbursement under DRG 216. On February 2, 2005, Rich Pilon, Director of Reimbursement, sent an email to all of the Sales and Reimbursement employees at Kyphon announcing, "[t]his is to inform you that there has been a change regarding DRG 216. The new relative weight for DRG 216 has been lowered to 1.8966. As a frame of reference, DRG 233 has a relative weight of 1.9542." Mr. Pilon's intention was to discourage the sales force from continuing the practice of promoting biopsies to increase reimbursement. Mr. Pilon was chastised by Kyphon Management for sending the e-mail to Kyphon employees. No change in Kyphon's sales message was made.

149. Many providers recognized that performance of a biopsy as a routine matter every time a Kyphoplasty was performed was not medically necessary and was simply a matter of securing additional reimbursement for hospitals and physicians. For example, Dr. Mangold, on

the Carrier Advisory Committee for Noridian, made this observation to Relator Patrick.

150. As a reasonably foreseeable consequence of Kyphon's ongoing marketing of unnecessary biopsies under DRG 216, numerous hospitals have submitted, and continue to submit, claims for reimbursement for unnecessary biopsies under DRGs 216.

151. Claims for unnecessary inpatient admissions coded under DRG 216 are false claims within the meaning of the Federal False Claims Act.

4. Kyphon Illegally Marketed Physician Reimbursement

152 From 1999-2005, Medicare carriers had divergent policies for coverage of kyphoplasty. Some carriers covered the procedure and directed providers to bill it under an unlisted code. Some carriers refused to cover the procedure at all for some period. Some would cover the procedure on a case by case basis after a review of records.

153 Even in parts of the country where coverage was available, many surgeons were resistant to using CPT Code 22899 because unlisted codes automatically get flagged for review by Medicare carriers. Kyphon trained its sales representatives to encourage doctors and their office staff to evade coverage determinations and to learn "alternative methods" of billing to increase reimbursement. Kyphon sales managers taught sales reps to persuade physicians that billing as "open reduction" is the most effective method for increasing reimbursement to the doctors. In training presentations, Kyphon describes the "open treatment and/or reduction" codes as "potentially related" CPT codes.

154. Kyphon sales training materials instructed sales representatives to advise physicians that, although kyphoplasty could be billed as an unlisted code, more profit could be earned by billing under CPT codes 22327, 22325, 22328 for open reduction of thoracic or lumbar vertebra.

155. Sales representatives were trained to misrepresent to doctor that it is acceptable to bill kyphoplasty under open codes because they are "reducing" the fracture.

156. In early years, open/reduction codes were used almost exclusively with surgeons in the Chicago area. Sales representative Roger Yapp encouraged physicians to bill under open reduction codes. Mr. Yapp was promoted to Regional Sales Manager.

157. Kyphon used other strategies to convince physicians to bill under open reduction codes and, thereby, realize a profit for kyphoplasty. For example, during one reimbursement presentation to physicians in Missouri, a Kyphon faculty member interrupted and "corrected" Relator Patrick and told all of the physicians present to bill the procedure under the "open" CPT code. Even though Mary K. Hailey, Kyphon's Vice President of Reimbursement, internally opposed using the "Open Reduction Codes" for reimbursement, her opinion was disregarded by Kyphon sales managers.

158. By billing kyphoplasty under CPT codes for open reduction, physicians could illegally obtain coverage of claims even from carriers with "no coverage " policies for kyphoplasty. Physicians could also avoid the review of their claim that would be triggered by billing under the unlisted code or by petitioning for coverage on a case by case basis.

159. Information about billing under "open reduction codes" was disseminated both directly and indirectly by Kyphon. For example, when Relator Bates started work at Kyphon and had reimbursement questions, he was told by his boss, Brad Paddock, a Regional Manager, to call another sales representative, David Ager. Mr. Paddock described Mr. Ager as "someone who knows how to make things happen."

160. Mr. Ager explained to Relator Bates that he would tell the doctors how to

bill for the procedure, but he would also direct doctors to contact other doctors to see how they billed for the procedure. Mr. Ager and other sales representatives, Dave Munro and Jim Lawless, had most of their surgeons using "open reduction codes" and were aware that the surgeons would share that information with doctors new to the procedure.

161. Billing kyphoplasty under an "open reduction" CPT code increases reimbursement significantly. Many physicians obtained reimbursement despite the carrier's no coverage policy and caused Medicare to pay for kyphoplasty when it would not have otherwise paid under that carrier's policies. Billing as open reduction also obtained more reimbursement for a physician than they would have received by billing under the unlisted code.

162. As a reasonably foreseeable consequence of Kyphon's misrepresentation to physicians that they could and should bill for kyphoplasty under open reduction codes, numerous physicians have submitted, and continue to submit, claims for reimbursement for kyphoplasty under open reduction codes.

163. Claims for reimbursement for kyphoplasty submitted under open reduction codes are false claims within the meaning of the Federal False Claims Act.

5. Additional Inducements Given to Physicians and Hospitals by Kyphon

a. Marketing Surgeon Practices to Obtain Referrals

164. Kyphon also provides physicians with other tangible and in-kind services to induce performance of kyphoplasties and sales of its product.

165. In order to persuade physicians to train to perform kyphoplasty, Kyphon sales representatives promised to market the practices of certain key physicians and the kyphoplasty procedure to referring physicians. Sales representatives also promised to mention the physician's

name in talk to seniors groups and to advertize the physician's services through the newspaper and in other media. .

166. In early 2003, Kyphon launched its Spine Education Specialist (SES) program. The purpose of the SES program became to extend the work of Kyphon's sales representatives by providing direct marketing support to key physicians, cultivating relationships with referral sources and identifying patients who would be eligible for kyphoplasty to refer to the surgeons.

167. Under the SES program, Kyphon identified key surgeons and targeted a SES to work with that surgeon and to identify physicians likely to refer to that surgeon. Then, the SES would ingratiate themselves with the PCP and their office staff and ask to review patient charts to identify patients who might be eligible for referral to the trained surgeon for kyphoplasty.

168. According to Anthony J. Recupero, Vice President of Sales at Kyphon, some of the initial criteria in determining where to place SES's were 1) states with high surgeon reimbursement, 2) territories with a large number active surgeons, 3) a significant number of top prescribing primary care physicians, 4) tenured spine consultants with excellent physician relationships, and 5) areas with extremely high potential for growth.

169. The SES program enhanced revenue growth for Kyphon and Kyphon-trained doctors by as much as double the average growth rate over the same period. The SES reps were paid by the company to"mine" for patients for doctors as a reward for performing the procedure. The compensation packages for SES reps were designed to spur referrals for kyphoplasty, setting quotas and paying SES reps a commission based on how many new kyphoplasty procedures were performed based on their referral work. .

170. A radiologist spoke at Kyphon's 2005 Annual Sales Conference and stated that his practice was happy to have the SES there because it was like having an extra employee.

171. SES reps cultivated patients for referral to high performing surgeons. Kyphon provided SES reps a "high subscriber" spreadsheet listing 19,000 prescribers of osteoporosis medications.

172. On April 12, 2005, Relator Patrick sent Mary Hailey, Richard Pilon, and all reimbursement managers a document explaining, *inter alia*, that it was a problem for Kyphon to be paying to generate referrals for doctors.

173. Shortly after Relator Patrick sent this memo, it was announced that the SES group would be disbanded. However, Kyphon sales representatives continue their referral and marketing support activity.

174. Relator Patrick also warned Kyphon managers about other areas of concern including Kyphon's marketing of physicians. Kyphon would send out marketing newsletters on behalf of doctors and pay for print ads for individual doctors. In addition, Kyphon sales representatives would draft letters to referring physicians on the surgeon's letterhead. Kyphon would pay for the cost of sending letters of behalf of the surgeon seeking referral of patients for kyphoplasty. .

175. Kyphon provides additional inducements to high performing physicians including paying them to be part of the Kyphon physician faculty and to speak to other doctors at Kyphon events; running ads promoting their practices in the newspapers; and other gratuities including paying for entertainment, providing expensive bottles of wine, and paying for dinners for physician spouses.

b. Kyphon Provides Free Equipment to Hospitals To Induce Procedures

176. Kyphon frequently gives free product to induce hospitals to perform kyphoplasty rather than vertebroplasty at their facility.

177. At a HCA hospital in Nashville, Tennessee, the hospital was not going to perform Kyphoplasty at all because of poor reimbursement for it as an outpatient procedure. In response, the hospital was told that Kyphon would give them free supplies for every outpatient procedure performed if the hospital would do inpatient procedures..

178. Sales representatives give hospitals free samples of products as an inducement to buy Kyphon products. Sales representatives were not limited to how many sample "kits" they could give away, so long as they tracked their samples. Sales representatives would ask hospitals for "No Charge Purchase Orders" so the sales representatives could later show the hospital how much free product the hospital received and how much money they saved using free products.

179. On October 18, 2005, Relator Patrick spent the morning with Tracy Wirtz, a Kyphon Spine Consultant based out of Minneapolis. Mr. Patrick and Ms. Wirtz visited Gundersen Lutheran Medical Center (GLMC) in La Crosse WI. Ms. Wirtz informed Mr. Patrick that the account is tough on price, "so in order to get them to do more cases we insure all cases are one level." According to Ms. Wirtz, Kyphon gives GLMC free kits whenever it is medically necessary to do anything more than one level of kyphoplasty. Ms. Wirtz is not aware that she is doing anything inappropriate and is following a practice that was understood and accepted by Kyphon management at the time. The arrangement with GLMC was in effect before Ms. Wirtz was assigned the account.

180. Kyphon provides free product to hospitals to induce them to perform

kyphoplasty. Kyphon routinely gives free product as an incentive to increase the number of kyphoplasty procedures. By receiving free product, hospitals reduce costs and increase reimbursement on each kyphoplasty performed.

181. Claims for reimbursement for kyphoplasty procedure from hospitals and physicians that have received kickbacks are not eligible for reimbursement by Medicare as adherence to the Anti Kickback Statute is a condition of payment.

182. Kickback-tainted claims for reimbursement are false claims within the meaning of the Federal False Claims Act.

COUNT I
False Claims Act
31 U.S.C. §3729(a)(1)

Plaintiffs realleges and incorporate by reference the allegations in paragraphs 1-182.

183. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729 *et seq.*

184. Through the acts described above, defendant Kyphon, Inc. knowingly presented, or caused to be presented, false or fraudulent claims, to the United States Government, in order to obtain government reimbursement for health care services provided under Medicare, Medicaid, and other Federal programs.

185. As a result of these false claims, the United States has been damaged and continues to be damaged, in an amount yet to be determined.

COUNT II
False Claims Act
31 U.S.C. §3729(a)(2)

Plaintiffs reallege and incorporate by reference the allegations in paragraphs 1-182.

186. This is a claim for treble damages and penalties under the False Claims Act,

31 U.S.C. §3729 *et seq.*

187. Through the acts described above, defendant Kyphon, Inc. has knowingly made, used and caused to be made and used false records and statements to get false or fraudulent claims paid in order to obtain government reimbursement for health care services provided under Medicare, Medicaid and other Federal programs.

188. As a result of these false claims, the United States has been damaged and continues to be damaged, in an amount yet to be determined.

COUNT III
False Claims Act
31 U.S.C. §3729(a)(7)

Plaintiffs reallege and incorporate by reference the allegations in paragraphs 1-182.

189. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729 *et seq.*

190. Through the acts described above, defendant Kyphon, Inc. has knowingly failed to disclose to the United States material facts in order to obtain government reimbursement for health care services provided under Medicare, Medicaid and other federal programs.

191. As a result of these false claims, the United States has been damaged and continues to be damaged, in an amount yet to be determined.

Prayer

WHEREFORE, plaintiffs pray for judgment against the defendant as follows:

1. that Defendant cease and desist from violating 31 U.S.C. §3729 et seq.;

2. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the United States has sustained because of Defendant's actions, plus a

civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. §3729;

3. that plaintiffs be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act;

4. that plaintiffs be awarded all costs of this action, including attorneys' fees and expenses; and

5. that the United States and plaintiffs recover such other and further relief as the Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, plaintiffs hereby demand a trial by jury.

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